GULF WAR RESEARCH STRATEGIC PLAN: 2011-2015

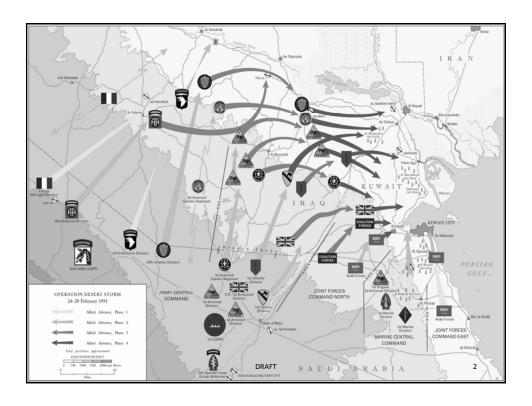
presented to the Research Advisory Committee on Gulf War Veterans' Illnesses

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Gulf War Research Strategic Plan for 2011-2015

- A body of research by VA, DoD, and others have shown:
 - Increased occurrence of a variety of reported symptoms,
 - o Certain successful treatments,
 - o Biomarkers associated with exposures, and
 - Other aspects of this condition.
- However, much remains to be done in research efforts.

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Gulf War Research Strategic Plan for 2011-2015

- The Steering Committee has developed a draft of a Gulf War Research Strategic Plan for 2011-2015, taking into account:
 - o Technological and scientific advances in recent years,
 - Previous research results, and
 - 。 RACGWVI and IOM reports.
- This strategic plan sets out goals and an implementation strategy to help improve the lives of suffering Gulf War Veterans.

Goals and Characteristics of Gulf War Strategic Plan

- Purpose: Provide a guide and framework for future research to improve the lives of Gulf War Veterans.
- Convert approved proposals to research accomplishment.
- Provide a basis for translating promising results to care.
- Be a living document that is reviewed periodically.

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Gulf War Research Strategic Plan 2011-2015

How is it Organized?
Summary of Strategic Objectives

Outline of Sections of the Plan

- Introduction
- Executive Summary
- Evolution of the Gulf War Research Strategic Plan
- Summary of Gulf War Research Results and Past Federal Support
- Gulf War Strategic Research Objectives
- Conclusions
- Bibliography

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Outline of Strategic Objectives

GULF WAR RESEARCH STRATEGIC OBJECTIVES 2011-2015

- Conduct Research to Enable Development of New Gulf War Case Definitions
- Genetics and Genomics
- Biomarkers
- Symptomatic and Specific Treatment
- Improve Coordination and Communication with Federal partners, Researchers, and the Private Sector.
- Translate Research Findings to Practice
- Animal Models

Elements of Strategic Objectives

GULF WAR RESEARCH STRATEGIC OBJECTIVES 2011-2015

- Five elements are presented for each strategic objective:
 - Statement of Objective
 - IOM Recommendations (quoted from IOM vol 8)
 - RACGWVI Recommendations (quoted from 2008 RACGWVI Report)
 - ORD Research or Activities
 - Research Plan

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Specific Example: Genetics/Genomics

- GWSP 5.2.1 Objective: Identify plausible hypotheses on the underlying causes and related pathways that might account for persistent symptoms in Gulf War Veterans.
- The IOM noted: "given the high prevalence of persistent symptoms and the steady advances in our understanding of genetics, molecular diagnostics, and imaging, it is now possible to plan and carry out adequately powered studies to identify inherited genetic variants, molecular profiles of gene expression, other epigenetic markers.
- The most recent RACGWVI report noted: "A question often asked about Gulf War illness is why some Gulf War military personnel developed chronic symptoms during and after deployment, while others who served alongside them remained well. There is more than one possible reason for this. Genetic and other differences between individuals can dictate different reactions to a given exposure.

Genetics/Genomics

Past Research Accomplished (example)

"Patterns of Microarray Gene Expression in Gulf War Illness" examined 20,000 genes by microarray immediately before and after an exercise challenge. Ill Gulf War Veterans demonstrated impaired immune function.

- Future Research Plans
 - MVP is a research program that will include Gulf War Veterans. It will allow current Veterans to help transform health care, not only for themselves, but for future generations of Veterans.
 - VA researchers will continue adding data and specimens to develop the research capacity of the ORD biorepository studies.

Specific Example: Treatments

- **GWSP 5.4.1 Objective:** Develop symptomatic and specific treatments for Gulf War Illnesses. Even if the mechanisms behind Gulf War Illnesses are not fully understood, it is possible to study and develop treatments that may improve a Veterans medical condition.
- The IOM noted that: "There is a dearth of organized clinical trials to examine potential treatments for the observed symptoms experienced by Gulf War Veterans.
- The RACGWVI noted that: "This complex of multiple concurrent symptoms typically includes persistent memory and concentration problems, chronic headaches, widespread pain, gastrointestinal problems, and other chronic abnormalities not explained by well-established diagnoses. No effective treatments have been identified for Gulf War illness and studies indicate that few Veterans have recovered over time."

Treatments

- Past Research Accomplished (example)
 - Nasal continuous positive airway pressure (nasal CPAP) for alleviation of symptoms, such as pain, fatigue, and cognitive function.
- Future Research Plans
 - Expand the number of "small projects" in the area of new treatments that could lead to larger studies.
 - Based on findings consider replicating promising "small projects" with larger studies at one or more additional sites.
 - Evaluate therapies including Mindfulness and treatments for Irritable Bowel Syndrome and other conditions.

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Specific Example: Biomarkers

- **GWSP Objective 5.3.1**: Identify biomarkers/diagnostics that may be present in ill Gulf War Veterans.
- The IOM noted: "Many of these symptoms (Gulf War) are difficult to categorize as they have no known cause, no objective findings on clinical examination, no diagnostic biomarkers, no known tissue pathology, and no curative therapy. The inadequate basic understanding of the root cause of these symptoms highlights the limitations of current medical science and clinical practice."
- The RACGWI noted: "Findings from studies of this type can therefore be affected by many of the problems described in relation to Gulf War illness research, that is, potential inaccuracies in identifying "exposed" vs. "unexposed" groups, the lack of useful biomarkers of exposure, and individual variability in specific exposures and vulnerability to those exposures. "

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Biomarkers

- Past Research Accomplished (example)
 Imaging biomarkers using MRI to show structural changes in brain tissue in Gulf War Veterans.
- Future Research Plans: Search for new biomarkers and validate them. These biomarkers include, but are not limited to:
 - Functional magnetic resonance imaging (fMRI) biomarkers to understand central nervous system mechanisms of pain and fatigue in Veterans with Gulf War Illness.
 - o Immune response mediator biomarkers that are associated with chronic inflammation.
 - o Hypothalamic-Pituitary-Adrenal axis biomarkers in chronic multisymptom illnesses.

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Gulf War Research Strategic Plan 2011-2015 Conclusions

Gulf War Research 2011-2015 Conclusions

- While progress has been made in Gulf War Research, much work remains to be done.
- This Gulf War Research Strategic Plan 2011-2015 has been formulated to guide the way forward in VA research.
- The Gulf War Research Strategic Plan 2011-2015 is a living document, and will be reviewed annually by the Gulf War Steering Committee, and other stakeholders, and updated as needed.

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Gulf War Research 2011-2015 Conclusions (cont)

- Strategic Plan will
 - Utilize new technology and concepts
 - Genomics/Genetics
 - Medical Imaging
 - Information Technology and Informatics
 - Build on findings related to treatments, biomarkers, imaging
 - Coordinate with appropriate entities within and outside of VA
 - Enhance communication among Gulf War Researchers by social media and other software
 - Utilize mechanisms for translation of research results

Discussion and Questions

Thank You!

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